

Appl. No. 10/702,193
Atty. Docket No. P123C
Amdt. dated February 14, 2007
Reply to Office Action of August 14, 2006
Customer No. 27752

REMARKS

Claim Status

Claims 1-19 are pending in the present application. No additional claims fee is believed to be due.

Information Disclosure Statement

The Examiner has indicated that the IDS filed January 30, 2004 fails to comply with 37 CFR 1.98(a)(1). Although an IDS had been submitted previously, for a related patent application to which the present application claims priority, and all references for the present IDS were the same as those for the prior IDS and such was stated in the submitted IDS, a listing of those references, with US patents and applications listed separately from other references, the application number with which the IDS was being submitted, a space for the Examiner to indicate consideration of the references, and a heading that identified the list as an IDS was not provided.

Submitted herewith is a USPTO form SB08, with a listing of references included for the previously listed IDS. As this submission is not an additional or supplemental IDS, but rather the required listing of references, it is not submitted as an IDS, but rather as an attachment to the present response. Thus, no fees are believed to be due with the submission of the listing of references.

The Applicant has thus provided the required listing of references, thereby bringing the previously submitted IDS into compliance with 37 CFR 1.98(a)(1). Therefore, the Applicant respectfully requests that the Examiner consider the IDS and the references submitted therewith by way of the attached listing of references.

Non-Statutory Double Patenting

Claims 1-19 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-52 of US patent 6,737,078 (the '078 patent). The Examiner asserts that although the claims are not identical to those of the '078 patent, the claims are anticipated. The Examiner indicates that a proper, timely-filed

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terminal disclaimer can be used to overcome the rejection. The Applicant will consider filing a terminal disclaimer when all other grounds for rejection have been overcome and the Examiner indicates that the present Claims are otherwise allowable.

Rejection Under 35 USC §103

I. Claims 1-19 are rejected under 35 USC §103(a) as being unpatentable over EP 0 678 247 A1 to Reinhart ("Reinhart") in view of US patent 5,110,592 to Stitt ("Stitt").

The Examiner asserts that Reinhart teaches a pet food comprising omega-6 and omega 3 fatty acids in ratios of from 3:1 to 10:1, fiber, minerals, carbohydrates, 30-34% protein, and 20-23% fat, used to "treat" and maintain animals such as dogs and cats. However, the Examiner acknowledges that Reinhart is silent as to using such a composition for enhancing or promoting reproductive performance. The Examiner asserts that Stitt teaches an animal blend comprising fatty acids to increase live births and improve fertility of animals, thus asserting that it would have been obvious to modify Reinhart's composition in view of the teaching of Stitt to achieve "at least similar" results because both references teach "advantageous results" in the use of fatty acid in companion animal food product.

The Applicant respectfully traverses the rejection. The Examiner has not established a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

As the Examiner noted, Reinhart does not provide any suggestion or motivation whatsoever to modify the document or combine the teachings with those of Stitt. Reinhart does not teach or suggest use fatty acids for anything with respect to reproduction. Reinhart only teaches using fatty acids in reducing allergic and inflammatory response in order to improve skin appearance. Thus, there can be no

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expectation of success for using fatty acids to enhance reproductive performance found in Reinhart. Because Reinhart does not disclose methods of enhancing reproductive performance, Reinhart does not teach or suggest all of the claim limitations.

Combination with Stitt also does not render the present Claims obvious. Stitt only discloses the use of omega-3 fatty acids, and teaches nothing with respect to use of omega-6 fatty acids for any purpose. Stitt discloses only omega-3 fatty acids derived from flaxseed, and their use in increasing the number of live births to a female animal, the only example of which, with respect to the invention of Stitt, is swine. Thus, Stitt provides no teaching, suggestion or motivation to use a combination of omega-3 and omega-6 fatty acids in any animal for any purpose. Thus, there is no expectation of success for using such a combination in any animal, for any purpose. Furthermore, because Stitt does not disclose omega-6 fatty acids, Stitt does not disclose all of the Claim limitations.

Therefore, the combination of Reinhart, which only discloses use of omega-3 and omega-6 fatty acids for improving skin health, with Stitt which only discloses use of omega-3 fatty acids for increasing live births in swine would not have led one of skill in the art to the Applicant's invention. Neither document, taken alone or in combination, provides the requisite suggestion or motivation to combine, nor any expectation of success. Furthermore, neither document alone, nor the two combined, disclose all of the Claim limitations.

Even assuming *arguendo* that Reinhart and Stitt could be combined, one would still fall short of the present invention, perhaps arriving at a composition using omega-3 and omega-6 fatty acids to improve skin health in swine.

Therefore, the rejection has been overcome and the Applicant respectfully requests withdrawal of the rejection.

II. Claims 1-16, 18 and 19 are rejected under 35 USC § 103(a) as being unpatentable over Reinhart in view of US patent 5,508,307 to Horrobin et al: ("Horrobin").

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The Examiner asserts that although Reinhart does not teach anything with respect to enhancing or promoting reproductive performance or increasing live births, it is "well known" in the pharmaceutical art that fatty acids are useful in treating reproductive disorders. The Examiner, cites, as an example, Horrobin for the disclosure that fatty acids such as omega-3 and omega-6 fatty acids, have "desirable effects" in a wide range of disorders including reproductive disorders. Thus, the Examiner asserts that it would have been obvious to "optimize" the compositions of Reinhart in view of Horrobin with the expectation of "at least similar" result because the cited documents teach "advantageous results" of essential fatty acids.

The Applicant respectfully traverses the rejection. The Examiner has not established a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

As noted above, and acknowledged by the Examiner, Reinhart suggests nothing with respect to fatty acids and reproductive performance. Thus, there is no suggestion, motivation or expectation of success to use fatty acids to enhance reproductive performance found in Reinhart. As noted above, Reinhart also does not disclose all of the Claim limitations.

Horrobin is directed to a method of administering, intravenously, fatty acids in their lithium salt form, to treat cancer in humans. The citation used by the Examiner in Horrobin (column 1, lines 9-35) simply states that different fatty acids *may* have desirable effects in a wide range of *disorders* including...reproductive disorders. The only animals mentioned in the examples of Horrobin are humans. There is no suggestion in Horrobin that any particular fatty acids or combinations thereof can be used in healthy animals to improve reproductive performance. The mere assertion that some fatty acids can be used to treat various disorders does not supply the requisite suggestion or

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motivation to use particular fatty acids in particular combinations or ratios to improve reproductive performance in animals. Thus, there is no expectation of success found in Horrobin for using fatty acids to enhance reproductive performance in animals. In addition, Horrobin does not disclose all of the Claim limitations because Horrobin does not disclose enhancing reproductive performance in animals.

Even assuming *arguendo* that Reinhart and Horrobin could be combined, one would still fall short of the present invention, perhaps arriving at methods to treat skin disorders in humans using lithium salts of fatty acids, or methods of treating cancer in animals using lithium salts of fatty acids.

Therefore, the rejection has been overcome and the Applicant respectfully requests withdrawal of the rejection.

III. Claims 1-19 are rejected under 35 USC §103(a) as being unpatentable over US patent 7,084,175 to Wilson ("Wilson") in view of Reinhart or US patent 4,474,874 to Shrimpton ("Shrimpton").

The Examiner asserts that Wilson teaches an animal feed composition having omega-3 and omega-6 fatty acids in ratios from 3:1 to 20:1, and that the composition is useful for increasing the reproductive performance of swine. As noted by the Examiner, Wilson does not teach anything with respect to dogs or cats. However, the Examiner asserts that it would have been obvious to modify the process of Wilson for cats or dogs because cats, dogs and swine are known to be "equivalent" mammals. The Examiner asserts that Reinhart teaches compositions useful for dogs, cats, horses, and more exotic animals such as guinea pigs. Swine, however, are not disclosed in Reinhart so the Examiner cited Shrimpton for Shrimpton's disclosure that the term "mammals" includes human, swine, dog and cat. Thus, the Examiner asserts that it would have been obvious to use the animal feed composition of Wilson for dogs or cats because Reinhart or Shrimpton discloses that swine, dog, or cat are "equivalent" mammals.

The Applicants assert that Wilson is an improper reference and can not be used in the rejection. See MPEP § 2141.01. Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the

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Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. . .

However, before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). Subject matter that is prior art under 35 U.S.C. 102 can be used to support a rejection under section 103. *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) ("it appears to us that the commentator [of 35 U.S.C.A.] and the [congressional] committee viewed section 103 as including all of the various bars to a patent as set forth in section 102."). See MPEP § 2141.01.

The earliest filing date of Wilson is that of a provisional application filed June 1, 2000. The Applicant's earliest filing date is based on a prior non-provisional application filed November 22, 2000 which claims priority to a provisional application, filed November 24, 1999. Thus, the earliest effective filing date of the present application is before that of Wilson. Therefore, Wilson is not a proper reference under 35 USC § 102 or 103.

However, even if Wilson were used as a reference and combined with Reinhart or Shrimpton, one would not arrive at the Applicant's invention. The Applicant respectfully traverses the rejection. The Examiner has not established a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

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combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

Wilson, as the Examiner noted, does not disclose using such compositions in animals other than swine. The only alternative animals disclosed in Wilson are different types of swine. See column 3, lines 2-8. Therefore, there is no suggestion, or expectation of success to use the compositions in animals other than swine, regardless of whether swine, dogs, cats and humans are all mammals. Because Wilson does not disclose such compositions and methods of using them to enhance reproductive performance in dogs or cats, Wilson does not disclose all of the Claim limitations.

Reinhart, as discussed above, does not disclose using such compositions for other than improving skin health. Thus, there is no suggestion, motivation or expectation of success for using such compositions to enhance reproductive performance in dogs and cats. Shrimpton is cited only for grouping dogs, cats, swine and humans as mammals.

Thus, neither Wilson, Reinhart nor Shrimpton taken alone or combination provide any suggestion, motivation or expectation of success for using the particular fatty acids, in the Claimed ratios to enhance reproductive performance in a companion animal.

Even assuming, *arguendo*, that Wilson, Reinhart and Shrimpton could be combined, one would still fall short of the present invention, perhaps arriving at compositions and methods for improving skin health in swine.

Therefore, the rejection has been overcome and the Applicant respectfully requests withdrawal of the rejection.

CONCLUSION

In light of the remarks presented herein, Applicants respectfully submit Claims 1-19 are allowable over the cited references. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicants' undersigned attorney for further discussion.

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Respectfully Submitted,

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